

## IBADAN KNEE/HIP OSTEOARTHRITIS OUTCOME MEASURE: PROCESS OF DEVELOPMENT

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### **ABSTRACT**

**The development of instruments for the assessment of therapeutic intervention has been an age long practice. However, many of the published instruments do not have detailed information on how the instruments were developed.**

**It is necessary for authors to provide detailed (step by step) information on how measuring scales/instruments are developed. The Ibadan Knee/Hip Osteoarthritis Outcome Measure (IKHOAM) was developed as a Nigerian-environment and culture-friendly instrument for the assessment of the effectiveness of therapeutic interventions in individuals with osteoarthritis of the knee and/or hip. This article outlines the steps involved in developing an outcome measure using IKHOAM as a template.**

### **INTRODUCTION**

Outcomes in clinical practice provide the mechanism by which the health care provider (HCP), the patient, the public, and the payer are able to assess the end results of care and its effect upon the health of the patient and society.<sup>1</sup> Measuring results of treatment in clinical setting has been an age long practice, however, the last three decades have witnessed the development of many standardized outcome measures in the health sector and effort has been redirected at integrating outcome assessment into clinical practice.<sup>1</sup> The major impetus to the development of standardized outcome measures in the health sector includes the demands of the third party payers of health care services and policy changes which have challenged health workers in developed countries to quantitatively account for the effectiveness of their therapeutic interventions more rigorously than before.<sup>1-2</sup>

The measurement of clinical outcomes in the health care delivery system is one of the most efficacious areas within the area of clinical decision making.<sup>3</sup> There is a shift from Health care provider (HCP) centeredness to customer centeredness in outcomes assessment. What is important in health care is what matters to the customers. Customers in the health transaction can now be patients, employers, governments, managed care organizations, insurance companies, HCP or society as a whole.<sup>4</sup> The methods of outcomes assessment, even in this currently evolving form may help provide tools that HCP can use to learn to focus on important attributes of care that not only meet accountability but patient satisfaction.

The development of instruments for the assessment of therapeutic intervention has been an age long practice. A number of well documented reliable and valid measures of functional health and activities of daily living (ADL) status have been developed for osteoarthritis. These include the Arthritis Impact Measurement Scales (AIMS)<sup>5</sup>, Knee Osteoarthritis Outcome Score (KOOS)<sup>6</sup>, Hip Osteoarthritis Outcome Score (HOOS)<sup>7</sup>, Western Ontario and McMaster University (WOMAC) Osteoarthritis Index<sup>8</sup>, Short Form (SF) 36 Arthritis Specific (SF 36 ASHI)<sup>9</sup>, Functional Status Index (FSI)<sup>10</sup>, Osteoarthritis Severity Indices of Lequesne (LEQUESNE)<sup>11-12</sup>, Health Assessment Questionnaire<sup>13</sup>, Ibadan Knee/Hip Osteoarthritis Outcome Measure (IKHOAM)<sup>14</sup>. According to McKay and Lyons, a standardized outcome measure refers to a published measurement tool, designed for a given population with detailed information on administration, scoring, interpretation and psychometric properties.<sup>15</sup> The Ibadan Knee/Hip Osteoarthritis Outcome Measure was developed as an environment and culture friendly tool for the assessment of therapeutic interventions in Nigerian patients with osteoarthritis of the knee and/or hip. However, many of these published existing instruments do not have all the detailed information on how the instruments were developed. There are many publications on IKHOAM but none has detailed information on how it was developed. In the development of IKHOAM, we discovered there was no simple to read information on the development of existing scales from our review of literature.

This stimulated the desire to write out this piece for healthcare providers intending to develop an indigenous tool for use in their environments.

### Methods in the development of IKHOAM

Prior to the development of IKHOAM, the question that arose was “Are existing outcome measures in osteoarthritis of the knee/hip suitable for the Nigerian environment?” The response to that question could be described as the first step in the development of IKHOAM

#### Step 1 - Finding Justification

A search of literature for all existing outcome measures in osteoarthritis of the knee/hip was conducted. A review of all published studies that included the use of outcome measures in the assessment of therapeutic interventions in patients with osteoarthritis of the hip and or knee was done through a PubMed search. Search terms used were “osteoarthritis of the knee”, “osteoarthritis of hip”, “rehabilitation”, “outcome assessment” and outcome measures. The date limit was from 1996-2000. Only 27 free full text articles were identified. Eight outcome measures were identified and copies of these measures were obtained from the authors. These outcome measures were the Knee Osteoarthritis Outcome<sup>6</sup>, Western Ontario and McMaster University Scale<sup>8</sup>, Osteoarthritis Severity Indices of Lequesne<sup>11-12</sup>, Arthritis Impact Measurement (AIMS) version 2<sup>5</sup>, Visual Analogue Scale<sup>16</sup>, Functional Status Questionnaire<sup>17</sup>, Stanford Health Assessment Questionnaire<sup>13</sup> and Short Form 36 Arthritis Specific<sup>18</sup>. They all have been translated into various languages (Swedish, Spanish, Italian, French, Dutch, Chinese etc.). The following limitations were observed in the existing instruments reviewed.

- i. All the identified published outcome measures had no contributions from Nigerian authors
- ii. The AIMS focus disproportionately on functional activities of joints of the upper limbs and OA of these joints are not common among Nigerian patients.
- iii. Some of these outcome measures include activities that the average Nigerian may not perform throughout life and a few items which may not be readily understood by those with low educational attainments. These items include:
  - a. Walking several blocks
  - b. Taking a tub bath
  - c. Vacuuming a rug
  - d. Turning faucets on and offFaucets are better known as taps in Nigeria, The average Nigerian is not familiar with the concept of a block being equal to 100 meters.

- iv. Almost all existing OA outcome measures excluded activities that are most important to many patients seen in the clinics. Such activities include:
  - a. Manual grass cutting/hoeing
  - b. Assuming the Islamic praying posture (sitting on the kneels)
  - c. Prostrating (by males) and incomplete kneeling (by females) to show courtesy to elders while greeting them.
  - d. Using pit/asiatic toilet
  - e. Sweeping with a short broom
  - f. Participating in coitus
  - g. Rising from matAll these reflect the socio-cultural and religious activities of an average Nigerian.
- v. Some of these outcome measures were rated by the patient alone and do not include items that are measured by the clinician.

According to McDowell and Newell, outcome measures that consist of both self/patient- and clinician/observer-measured items are being recommended over patient-administered ones so as to minimize belief mismatch, a problem that has been associated with patient-administered tools.<sup>19</sup> Based on the review of existing outcome measures and limitations found, we decided to develop IKHOAM. The Ibadan Knee/Hip Osteoarthritis Outcome Measure was developed as both patient- and clinician-administered scale that was appropriate for the Nigerian environment and culture.<sup>14</sup> According to McKay and Lyons, a standardized outcome measure refers to a published measurement tool, designed for a given population with detailed information on administration, scoring, interpretation and psychometric properties.<sup>15</sup>

#### Step 2 - Defining the purpose/conceptual basis

The conceptual basis of IKHOAM was that in osteoarthritis of the knee and/or hip, certain functional limitations occur. It was therefore developed noting key areas of difficulty and changes in the physical functioning of patients with knee and hip osteoarthritis that relate to the Nigerian culture and environment. IKHOAM was made specific to osteoarthritis of the knee and hip because these are the two joints most frequently affected by osteoarthritis among Nigerians.

#### Step 3 - Devising the items

Items on IKHOAM were generated through the following means;

- a. Literature review: Literature review showed that certain activities were common in most osteoarthritis outcome measures. These activities were probably those deemed relevant and

important to individuals with osteoarthritis of the knee/hip by previous developers. These activities include walking long distance, putting on under-cloth, climbing/descending stairs, walking outdoors, standing up from a straight chair, getting in and out of bed, getting in and out of a car, performance at work, participation in community activities such as religious services, social activities or volunteer work.

- b. Patients' interview: Twenty-five patients with knee/hip osteoarthritis who were attending physiotherapy out-patient clinics of the University College Hospital, Ibadan, Nigeria were interviewed in order to identify functional activities/physical performance tests which patients had problems with and those that were important to them. The functional activities identified were:
  - i. Manual grass cutting/hoeing
  - ii. Assuming the Islamic praying posture (sitting on the kneels)
  - iii. Prostrating (by males) and incomplete kneeling (by females) to show courtesy to elders while greeting them.
  - iv. Using pit/asiatic toilet
  - v. Sweeping with a short broom
  - vi. Participating in coitus
  - vii. Rising from mat
  - viii. Hand-washing of clothes at floor level
- c. Clinical experience of expert physiotherapists: Five physical performance tests deemed relevant and important were identified based on the clinical experience of 3 physiotherapists who had a minimum of 10 years working experience. The 5 tests are leg stance test, walk test, stairs climbing test, squat test, and balance test.

#### **Step 4 - Content validation**

A checklist of all the items generated was sent to 8 physiotherapists with minimum of 10 years working experience and 3 consultant orthopedic surgeons from the University College Hospital, Ibadan, Nigeria. The physiotherapists were selected based on their years of clinical experience and research activities on outcome assessment while the orthopedic surgeons were all the consultants as at the time of the commencement of the development of IKHOAM. Detailed explanation about the conceptual basis and purpose for the development of IKHOAM was given to them. They were asked to assess the content coverage and relevance of the items. They also evaluated the appropriateness of the generated items to ensure that all important dimensions of function were included. After taking their comments and suggestions, a second draft of the checklist was produced and it was assessed by 24 physiotherapists from 6 other tertiary health institutions

and 6 secondary health institutions in South-western geopolitical zone of Nigeria during a focus group discussion. Using their comments and suggestions a third draft was produced.

#### **Step 5 - Scaling responses**

The scaling responses for the patient-administered parts of IKHOAM were adopted from the World Health Organization's checklist for clinical trials of the International Classification of Impairments, Disability and Handicap (ICIDH, beta-2)<sup>20</sup>. A pilot study involving 10 patients with knee or hip OA and 10 age- and sex-matched apparently healthy individuals without knee or hip pain was conducted in order to determine the ratings on the physical performance tests. The data served as a guide to the possible limits of performance on each test. The grading was based on mean scores of apparently healthy individuals (upper limit) and of the OA patients (lower limit).

#### **Step 6 - Selecting the items**

The third draft of the check list with the scaling responses for the three parts of IKHOAM was produced as the initial draft of the instrument under development. It was pre-tested on 15 patients with OA knee/hip receiving physiotherapy at the out-patient clinic of the physiotherapy department, University College Hospital, Ibadan, Nigeria. The aim of the pre-testing was to eliminate ambiguous, double barreled and incomprehensible items. Following the pre-testing, some items were reported to be ambiguous and double barreled. This initial draft of IKHOAM was revised by a committee of 4 experts (physiotherapists) and target population (patients with osteoarthritis) to produce the final draft of IKHOAM which was administered on 49 patients to assess the frequency of endorsement of the items. The frequency of endorsement of all items was found satisfactory (29%-79%) as suggested by Streiner and Norman.<sup>21</sup> The frequency of endorsement is the proportion of people who give each response alternative to an item.<sup>21</sup>

#### **Step 7- Minimizing biases in responses**

In order to minimize yea-saying biases (tendency to give positive response irrespective of the contents of the item) in the responses on IKHOAM, all the items were re-ordered so that the domains of coverage were not too evident to the respondents.

#### **Step 8 - Other considerations**

##### *Naming*

The Ibadan Knee/Hip Osteoarthritis Outcome Measure (IKHOAM) was named to reflect that it is a disease-specific scale meant to assess outcomes of treatment of patients with knee/hip OA. It was also

named to reflect that the scale was developed at the University of Ibadan, Ibadan.

## DESCRIPTION

The Ibadan Knee/Hip Osteoarthritis Outcome Measure (IKHOAM) is a 3-domain/part, 33- item instrument. The domains are:

- a. Activity limitations domain (part 1) - comprises 25 items/activities of daily living that are being performed by individuals with knee/hip osteoarthritis. The degree of difficulty and assistance required in carrying out the activities are rated on a 5 point (0-4) ordinal scale.
- b. Participation restrictions domain (part 2) – comprises 3 items/activities in societal participation due to knee/hip osteoarthritis. The restrictions experienced in carrying out the activities are rated on a 4 point (0-3) ordinal scale.
- c. Physical performance tests domain (part 3) – includes 5 tests that are rated by the clinician. These tests are;
  - (i) 250m walk test rated on a 6 point (0-5) ordinal scale.
  - (ii) One leg stance test rated on a 6 point (0-5) ordinal scale.
  - (iii) Stairs climbing test rated on a 5 point (0-4) ordinal scale.
  - (iv) Squat test rated on a 5 point (0-4) ordinal scale.
  - (v) Balance test rated on a 6 point (0-5) ordinal scale.

Parts 1 and 2 are patient report, which may be completed by the patient (self) or through interview. It takes about 15 minutes to complete IKHOAM.

## Scoring

Part one: Maximum obtainable score of 200. Degree of difficulty and nature of assistance required for each of 25 items were scored between 0 and 4 each.

Part two: Extent of participation in performing the three items was scored between 0 and 3 giving a maximum obtainable score of 9.

Part three: Maximum obtainable score of 23 (5 for 250m walk test, 5 for one leg stance test, 4 for stairs climbing test, 4 for squat test, 5 for balance test).

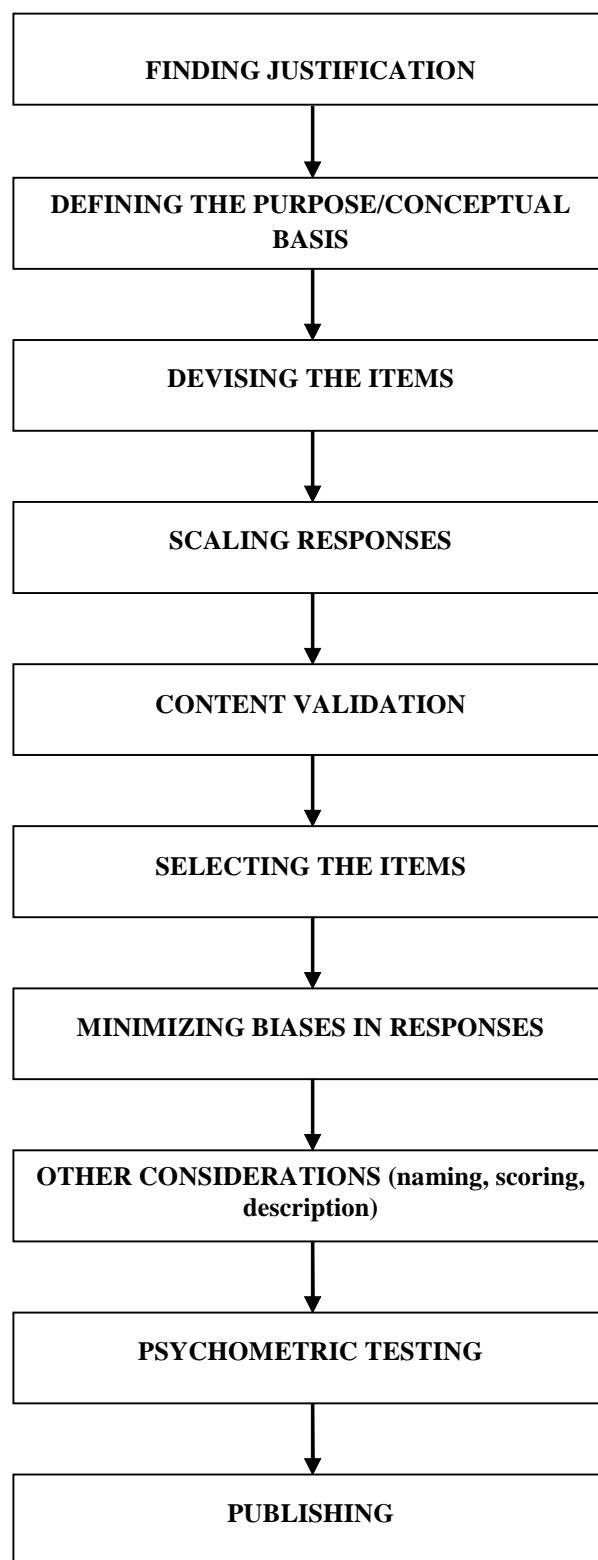
The maximum obtainable score on IKHOAM is 232 (200+9+23). The score for a subject was calculated in percentage as  $\frac{\text{Subject's score}}{\text{Total possible score}} \times 100$

Low score on IKHOAM implies low level of physical functioning ability and high level means high level of physical functioning ability.

## Step 9 – Psychometric testing

The IKHOAM has been tested for validity<sup>14</sup>, responsiveness<sup>14</sup>, reliability<sup>22</sup>, Minimal Clinical

Important Difference<sup>23</sup>. To enhance its utility, translated versions in the three major Nigerian languages are available with evidence of psychometric properties.<sup>24-27</sup>



**Figure 1:** Flow chart of the steps involved in the development of IKHOAM

## Step 10 - Publishing

Several articles on IKHOAM have been published in peer review journals.<sup>14, 20-25</sup>

The development of IKHOAM was approved by the University of Ibadan/University College Hospital Research Ethics Committee. All the steps involved in the development of IKHOAM are presented in figure 1

## CONCLUSION

The development of a new measuring scale involves a lot of effort no matter how simple the scale appears to be. It is important that developers of new scales ensure that they go through the necessary steps in the development of such scales. The Ibadan Knee/Hip Osteoarthritis Outcome Measure was developed as a measuring instrument that is both patient- and clinician administered and appropriate for the Nigerian and similar environment. It is necessary that indigenous outcome measures are available for use and intending developers may find this article worth reading.

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